**Application No.:** 10/009,097

Office Action Dated: November 15, 2004

PATENT REPLY FILED UNDER EXPEDITED PROCEDURE PURSUANT TO 37 CFR § 1.116

This listing of claims will replace all prior versions, and listings, of claims in the application. Listing of Claims:

1. (Previously Presented) A gel fraction of psyllium seed husks that survives microbial fermentation upon passage through a monogastric mammalian digestive tract, said fraction comprising xylose and arabinose in a dry weight ratio of at least about 2.5:1 to about 4.5:1, and further comprising less than about 2% (by weight) rhamnose.

2. (Original) The gel fraction of claim 1, wherein the xylose to rhamnose dry weight ratio is greater than 50.

3. (Original) The gel fraction of claim 1, which comprises galactose, having a xylose to galactose dry weight ratio that is greater than 25.

4. (Original) The gel fraction of claim 1, which comprises uronic acids, having a xylose to uronic acids dry weight ratio that is greater than 25.

5. (Previously Presented) The gel fraction of claim 1, having a sugar composition, based on percent dry weight, of:

between about 0 and 4% rhamnose;

between about 15 and 22% arabinose;

between about 55 and 76% xylose;

between about 0 and 0.5% mannose;

between about 1 and 2% galactose

between about 0 and 1% glucose; and

between about 0.5 and 6% uronic acids.

6. (Original) The gel fraction of claim 1, having an apparent viscosity in formamide of at least 500 sec.

7. (Original) The gel fraction of claim 1, which is soluble in a dilute alkaline solution and which forms a gel upon acidification of the solution to a final pH of about 4.5.

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8. (Original) A pharmaceutical preparation for treatment of constipation in a patient in need of such treatment, comprising an effective dose of the gel fraction of claim 1.

- 9. (Original) The pharmaceutical preparation of claim 8, wherein the effective dose is between about 2 and about 6 g, based on dry weight, of the gel.
- 10. (Original) A pharmaceutical preparation for treatment of high blood cholesterol in a patient in need of such treatment, comprising an effective dose of the gel fraction of claim 1.
- 11. (Original) The pharmaceutical preparation of claim 10, wherein the effective dose is between about 3 and about 7 g, based on dry weight, of the gel.
- 12. (Currently Amended) A carbohydrate fraction of psyllium seed husks, said fraction being soluble in a dilute alkaline solution and remaining soluble upon acidification of the solution to a pH of about 4.5, said fraction comprising xylose and arabinose in a ratio of at least about 4:1, further comprising at least about 12% (by weight) rhamnose and at least about 15% (by weight) uronic acid, and further comprising galactose wherein the ratio of the dry weight of the xylose to that of the galactose is more than about 20:125:1.

## 13-17. Canceled.

- 18. (Previously Presented) A gel fraction from psyllium seed husks, produced by a method comprising:
- (a) mixing the husks in an aqueous solution comprising a base, wherein if the base comprises hydroxyl ions, the concentration of hydroxyl ions is between about 0.15 M and 1.0 M; thereby fractionating the husks into an alkali soluble fraction and an alkali-insoluble fraction;
  - (b) removing the alkali-insoluble fraction;
- (c) acidifying the alkali soluble fraction to a pH of between about 3 and 6, thereby obtaining an acid-insoluble gel fraction, and an acid-soluble fraction; and
  - (d) separating the gel fraction from the solution containing the acid-soluble fraction.

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19. (Original) A pharmaceutical preparation for treatment of constipation in a patient in need of such treatment, comprising an effective dose of the gel fraction of claim 18.

20. (Original) The pharmaceutical preparation of claim 19, wherein the effective dose is between about 2 and about 6 g, based on dry weight, of the gel.

21. (Original) A pharmaceutical preparation for treatment of high blood cholesterol in a patient in need of such treatment, comprising an effective dose of the gel fraction of claim 18.

22. (Original) The pharmaceutical preparation of claim 21, wherein the effective dose is between about 3 and about 7 g, based on dry weight, of the gel.

## 23. Canceled.

- 24. (Previously Presented) A method of treating constipation in a patient in need of such treatment, which comprises administering to the patient, in an amount and for a time effective to relieve the constipation, a preparation comprising an isolated gel-forming fraction from psyllium seed husks that survives microbial fermentation upon passage through a monogastric mammalian digestive tract, said fraction comprising xylose and arabinose in a dry weight ratio of at least about 2.5:1 to about 4.5:1, and further comprising less than about 2% (by weight) rhamnose.
- 25. (Previously Presented) A method of treating constipation in a patient in need of such treatment, which comprises administering to the patient, in an amount and for a time effective to relieve the constipation, a preparation comprising a gel fraction from psyllium seed husks, the gel fraction being produced by a method comprising:
- (a) mixing the husks in an aqueous solution comprising a base, wherein if the base comprises hydroxyl ions, the concentration of hydroxyl ions is between about 0.15 M and 1.0 M; thereby fractionating the husks into an alkali soluble fraction and an alkali-insoluble fraction;
  - (b) removing the alkali-insoluble fraction;

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(c) acidifying the alkali soluble fraction to a pH of between about 3 and 6, thereby obtaining an acid-insoluble gel fraction, and an acid-soluble fraction; and

- (d) separating the gel fraction from the solution containing the acid-soluble fraction.
- 26. (Previously Presented) A method of lowering serum cholesterol in a patient in need of such treatment, which comprises administering to the patient, in an amount and for a time effective to lower the patient's serum cholesterol, a preparation comprising an isolated gel-forming fraction from psyllium seed husks that survives microbial fermentation upon passage through a monogastric mammalian digestive tract, said fraction comprising xylose and arabinose in a dry weight ratio of at least about 2.5: 1 to about 4.5: 1, and further comprising less than about 2% (by weight) rhamnose.
- 27. (Previously Presented) A method of lowering serum cholesterol in a patient in need of such treatment, which comprises administering to the patient, in an amount and for a time effective to relieve the constipation, a preparation comprising a gel fraction from psyllium seed husks, the gel fraction being produced by a method comprising:
- (a) mixing the husks in an aqueous solution comprising a base, wherein if the base comprises hydroxyl ions, the concentration of hydroxyl ions is between about 0.15 M and 1.0 M; thereby fractionating the husks into an alkali soluble fraction and an alkali-insoluble fraction;
  - (b) removing the alkali-insoluble fraction;
- (c) acidifying the alkali soluble fraction to a pH of between about 3 and 6, thereby obtaining an acid-insoluble gel fraction, and an acid-soluble fraction; and
  - (d) separating the gel fraction from the solution containing the acid-soluble fraction.
- 28. (Previously Presented) A composition comprising an isolated gel-forming fraction from psyllium seed husks that survives microbial fermentation upon passage through a monogastric mammalian digestive tract, said fraction comprising xylose and arabinose in a dry weight ratio of at least about 2.5:1 to about 4.5:1, and further comprising less than about

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2% (by weight) rhamnose; and an isolated acid-soluble fraction of psyllium seed husk, the acid-soluble fraction having at least 25% xylose and arabinose by weight.

29. (Previously Presented) A pharmaceutical preparation comprising the composition of claim 28.